REMARKS

Claims 1-8, 10-15, 18, 24-26, and 42-46 are pending. Claims 1-8, 10-15, 18, 24-26, and 42-46 have been canceled without prejudice and new claims 48-56 have been added to more particularly point out what applicant regards as the invention. The specification has been amended to insert Sequence Identifiers where appropriate and to correct grammatical errors. Support for new claims 48-56 is found in the specification, *inter alia*, as indicated in the table attached hereto as **Exhibit A**. Applicant submits that these Amendments raise no issue of new matter. Thus, claims 48-56 will be pending and under examination upon entry of this Amendment.

In view of the arguments set forth below, applicant maintains that the Examiner's remarks made in the March 17, 2004 Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw the outstanding rejections.

Formalities

Objection to the Oath

The Examiner objected to the Oath as defective because it does not identify the inventor's mailing address. In response, applicant has provided the required information in an Application Data Sheet attached hereto as **Exhibit B**.

Objection regarding April 10, 2000 substitute sequence listing

The Examiner objected to applicant's substitute sequence listing submitted on April 10, 2000 because, while it included a statement that the substitute CRF and the paper copy of the

sequence listing were the same, there was no statement to the effect that the substitute sequence listing contained no new matter. In response, applicant submits herewith as **Exhibit C**, a statement that applicant's April 10, 2000 substitute sequence listing contains no new matter.

Rejections Under 35 U.S.C. '112, First Paragraph

The Examiner rejected claims 1-8, 10-15, 18, 24-26, and 42-46 under 35 U.S.C. '112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

In response to the Examiner's rejection, applicant maintains that the specification adequately describes the claimed invention for reasons of record and for the additional reasons set forth below.

Applicant addresses the Examiner's rejection as it applies to new claims 48-56.

Possession may be shown in a variety of ways including description of an actual reduction to practice or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. M.P.E.P. §2163.02.

The specification demonstrates possession of the chimeric proteins of the claims both by actual reduction to practice and by describing distinguishing identifying characteristics

of these proteins, namely their preference for methylation of specific target sequences.

The LexA-M.SssI DNAmt chimera is described in the specification at page 6, lines 14-22 (Fig. 6), and page 8, lines 6-29 (Fig. 11). Specifically, Figure 6 shows a schematic of the vector for producing the LexA-M.SssI protein, which also includes the target methylation site. Figure 11 depicts experimental data demonstrating that the LexA-M.SssI chimera has the distinguishing identifying characteristic of preferentially methylating a CpG site near the LexA DNA binding site.

The LacI-M.SssI DNAmt chimera is described in the specification at page 8, lines 31-35 (Fig. 12), and page 9, lines 1-29 (Figs. 12-14). Specifically, Figure 12 shows a schematic of the vector for producing the LacI-M.SssI protein, which also includes the target methylation site. Figure 13 depicts experimental data demonstrating expression of the LacI-M.SssI protein. Figure 14 depicts experimental data demonstrating that the LacI-M.SssI chimera has the distinguishing identifying characteristic of preferentially methylating a CpG site near the LacI DNA binding site.

The protocol for producing the chimeric proteins of the instant claims is detailed in Example 1, pages 39-42, and in the Brief Description of the Figures.

Applicant maintains that one of skill in the art would recognize from the teachings of the instant specification that applicant was in possession of the claimed invention.

The Examiner also rejected claims 1-8, 10-15, 18, 24-26, and 42-46 under 35 U.S.C. '112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to allow one skilled in the relevant art to which it pertains to make and/or use the invention commensurate in scope with the claims.

In response, applicant respectfully traverses for the reasons of record and for the additional reasons set forth below as applied to new claims 48-56.

The Examiner alleged that undue experimentation is required to practice the claimed invention. The fact that experimentation may be complex does not necessarily make it undue, if the art typically teaches engaging in such experimentation. M.P.E.P. §2164.01. It is the undue nature of experimentation, and not its quantity, which is incompatible with enablement.

The specification combined with the knowledge in the art provides detailed information regarding the structures of the proteins which make up the instant chimeras, as well as the correlation between those structures and the proteins' functions. For example, the amino acid structure and functional properties of M.SssI methyltransferase and the LexA DNA binding protein were well-known in the art at the time of filing (see page 39, lines 3-10, of the specification). Likewise, the structure and function of the Lac repressor, LacI and its DNA binding sequence, LacO, have been known for decades.

It is undisputed by the Examiner that the level of skill in the art of producing functional chimeric proteins is high. Applicant maintains that the instant invention can be

practiced without undue experimentation given the knowledge and skill in the art combined with the guidance provided in the instant specification, such as the specific examples of LexA-M.SssI DNAmt, LacI-M.SssI DNAmt, and Zif268-M.SssI DNAmt fusion proteins.

Finally, the Examiner rejected claims 44-46, directed to pharmaceutical compositions, because there is allegedly no evidence of record that the claimed composition can be used successfully to treat, prevent, or ameliorate any disease.

In response, applicant notes that these claims have been canceled and there are no corresponding new claims. Therefore the rejection is moot.

In view of the above remarks, applicant maintains that new claims 48-56 satisfy the requirements of U.S.C. '112, first paragraph.

Summary

In view of the remarks made herein, applicant maintains that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

6/07/04
Alan J. Morrison Date
Reg. No. 37,399

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

EXHIBIT A

New Claim	Corresponding Previous Claim	Support in the Specification
48	1, 5, 6	p. 12, lines 11-19 (chimeric protein) p. 13, lines 3-15 (methyltransferase, M.SssI, CpG) p. 14, lines 28-32 (specifically methylates) p. 39, lines 13-15 (M.SssI DNAmt methylates in vicinity of LexA binding site) p. 45, lines 28-35 (DNA binding region adjacent to CpG sites)
49	7, 8	p. 15, lines 10-23; p. 23, lines 6-19 (vector comprising chimeric proteins)
50		p. 6, lines 14-22,p. 8, lines 6-29, and Figures 6 and 11; (vector comprising LexA-M.SssI fusion protein and LexA DNA binding site, at least one CpG adjacent to DNA binding site)
51		p. 45, lines 28-35 (DNA binding region adjacent to CpG sites; approximately a 25 base pair spacer between them)
52	1, 4, 6	p. 8, lines 32-35, page 9, lines 1-29, and Figs. 12-14 (LacI-M.SssI protein which preferentially methylates CpG sites in the vicinity of Lac operator sequence)
53		same as for new claim 52
54		same as for new claim 52
55		same as for new claim 52
56	42	p. 75